IEC 62366-1

Edition 1.0 2015-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical devices –
Part 1: Application of usability engineering to medical devices

Dispositifs médicaux –
Partie 1: Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux

IEC 62366-1:2015-02(en-fr)

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MEDICAL DEVICES –

Part 1: Application of usability engineering to medical devices

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 62366-1 has been prepared by a joint working group of subcommittee 62A: Common aspects of electrical medical equipment used in medical practice, of IEC technical committee 62: Electrical medical equipment in medical practice, and ISO technical committee 210: Quality management and corresponding general aspects for MEDICAL DEVICES.

It is published as double logo standard.

This first edition of IEC 62366-1, together with the first edition of IEC 62366-2, cancels and replaces the first edition of IEC 62366 published in 2007 and its Amendment 1 (2014).

Part 1 has been updated to include contemporary concepts of USABILITY ENGINEERING, while also streamlining the process. It strengthens links to ISO 14971:2007 and the related methods of RISK MANAGEMENT as applied to SAFETY related aspects of medical device user interfaces. Part 2 contains tutorial information to assist manufactures in complying with Part 1, as well as offering more detailed descriptions of USABILITY ENGINEERING methods that can be applied

more generally to MEDICAL DEVICES that go beyond safety-related aspects of MEDICAL DEVICE USER INTERFACES.

The text of this standard is based on the following documents:

FDIS	Report on voting
62A/977/FDIS	62A/988/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 26 P-members out of 26 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this International Standard, the following print types are used:

– Requirements and definitions: roman type.
– *Means to assess compliance: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type
– TERMS DEFINED IN CLAUSE 3 OR AS NOTED: SMALL CAPITALS.

The requirements are followed by means to assess compliance.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses and subclauses for which a rationale is provided in informative Annex A are marked with an asterisk (*).

A list of all parts of the IEC 62366 series, published under the general title *Medical devices,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

– reconfirmed,
– withdrawn,
– replaced by a revised edition, or
– amended.

NOTE The attention of National Committees and Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

Medical practice is increasingly using MEDICAL DEVICES for observation and treatment of PATIENTS. USE ERRORS caused by inadequate MEDICAL DEVICE USABILITY have become an increasing cause for concern. Many of the MEDICAL DEVICES developed without applying a USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS are non-intuitive, difficult to learn and difficult to use. As healthcare evolves, less skilled USERS including PATIENTS themselves are now using MEDICAL DEVICES and MEDICAL DEVICES are becoming more complicated. The design of the USER INTERFACE to achieve adequate USABILITY requires a different PROCESS and skill set than that of the technical implementation of the USER INTERFACE.

The USABILITY ENGINEERING PROCESS is intended to identify and minimise USE ERRORS and thereby reduce use-associated RISKS. Some, but not all, forms of incorrect use are suited to control by the MANUFACTURER. The USABILITY ENGINEERING PROCESS is related to the RISK MANAGEMENT PROCESS as indicated in Figure A.4.

This International Standard describes a USABILITY ENGINEERING PROCESS to provide acceptable RISK related to USABILITY of a MEDICAL DEVICE. It is intended to be useful not only for MANUFACTURERS of MEDICAL DEVICES, but also for technical committees responsible for the preparation of particular MEDICAL DEVICE standards.

This International Standard strictly focuses on applying the USABILITY ENGINEERING PROCESS to optimize MEDICAL DEVICE USABILITY as it relates to SAFETY. The companion technical report (IEC 62366-2[1]) is comprehensive and has a broader focus. It focuses not only on USABILITY as it relates to SAFETY, but also on how USABILITY relates to attributes such as TASK accuracy, completeness and EFFICIENCY, and USER satisfaction.

NOTE SAFETY is freedom from unacceptable RISK. Unacceptable RISK can arise from USE ERROR, which can lead to exposure to direct physical HAZARDS or loss or degradation of clinical functionality.

MANUFACTURERS can choose to implement a USABILITY ENGINEERING program focused narrowly on SAFETY or more broadly on SAFETY and other attributes, such as those cited above. A broader focus might also be useful to address specific USABILITY ENGINEERING expectations, such as the need to confirm that USERS can successfully perform non-SAFETY-related TASKS. A MANUFACTURER might also implement a broader program to realize the commercial benefits of a MEDICAL DEVICE that not only is safe to use but also offers superior USABILITY.

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1 IEC 62366-2, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices* (in preparation).

MEDICAL DEVICES –

Part 1: Application of usability engineering to medical devices

1 * Scope

This part of IEC 62366 specifies a PROCESS for a MANUFACTURER to analyse, specify, develop and evaluate the USABILITY of a MEDICAL DEVICE as it relates to SAFETY. This USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS permits the MANUFACTURER to assess and mitigate RISKS associated with CORRECT USE and USE ERRORS, i.e., NORMAL USE. It can be used to identify but does not assess or mitigate RISKS associated with ABNORMAL USE.

NOTE 1 SAFETY is freedom from unacceptable RISK. Unacceptable RISK can arise from USE ERROR, which can lead to exposure to direct physical HAZARDS or loss or degradation of clinical functionality.

NOTE 2 Guidance on the application of USABILITY ENGINEERING to MEDICAL DEVICES is available in IEC 62366-2[2], which addresses not only SAFETY but also aspects of USABILITY not related to SAFETY.

If the USABILITY ENGINEERING PROCESS detailed in this International Standard has been complied with, then the USABILITY of a MEDICAL DEVICE as it relates to SAFETY is presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary.

NOTE 3 Such OBJECTIVE EVIDENCE can subsequently originate from POST-PRODUCTION surveillance.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the bibliography beginning on page 46.

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

For the purpose of this document, the terms and definitions given in ISO 14971:2007 and the following apply.

NOTE An index of defined terms is found beginning on page 49.

3.1
*** ABNORMAL USE**
conscious, intentional act or intentional omission of an act that is counter to or violates NORMAL USE and is also beyond any further reasonable means of USER INTERFACE-related RISK CONTROL by the MANUFACTURER

EXAMPLES Reckless use or sabotage or intentional disregard of information for SAFETY are such acts.

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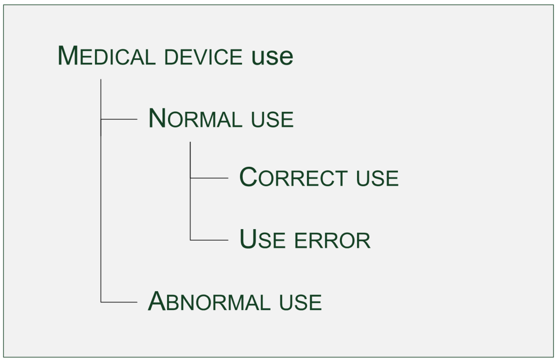
2 IEC 62366-2, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices* (in preparation).

Note 1 to entry See also 4.1.3.

Note 2 to entry: An intended but erroneous action that is not ABNORMAL USE is considered a type of USE ERROR.

Note 3 to entry: ABNORMAL USE does not relieve the MANUFACTURER from considering non-USER INTERFACE-related means of RISK CONTROL.

Note 4 to entry: Figure 1 shows the relationships of the types of use.



IEC

NOTE Figure D.1 contains additional detail

Figure 1 – Relationship of the types of use

3.2
ACCOMPANYING DOCUMENTATION

materials accompanying a MEDICAL DEVICE and containing information for the USER or those accountable for the installation, use and maintenance of the MEDICAL DEVICE, particularly regarding safe use

Note 1 to entry: The ACCOMPANYING DOCUMENTATION can consist of the instructions for use, technical description, installation manual, quick reference guide, etc.

Note 2 to entry: ACCOMPANYING DOCUMENTATION is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types.

Note 3 to entry: MEDICAL DEVICES that can be used safely without instructions for use are exempted from having instructions for use by some authorities with jurisdiction.

[SOURCE: ISO 14971:2007, 2.1, modified – The term has been changed to refer to ‘documentation’ rather than ‘document’, and in the definition ‘document’ has been replaced by ‘material’, ‘OPERATOR’ has been deleted and notes to entry have been added.]

3.3
CORRECT USE

NORMAL USE without USE ERROR

Note 1 to entry: Deviation from instructions for use is only considered USE ERROR if it leads to a MEDICAL DEVICE response that is different than intended by the MANUFACTURER or expected by the USER.

Note 2 to entry: Figure 1 shows the relationships of the types of use.

3.4
EFFECTIVENESS

accuracy and completeness with which USERS achieve specified goals

Note 1 to entry: This is a different concept than 'clinical effectiveness'.

[SOURCE: ISO 9241-11:1998, 3.2, modified – Added the note to entry.]

3.5
*** EFFICIENCY**
resources expended in relation to EFFECTIVENESS

[SOURCE: ISO 9241-11:1988, 3.3, modified – the term "EFFECTIVENESS" has replaced the original phrase, which here constitutes the definition of 3.4 EFFECTIVENESS.

3.6
EXPECTED SERVICE LIFE
time period specified by the MANUFACTURER during which the MEDICAL DEVICE is expected to remain safe for use (i.e. maintain basic SAFETY and essential performance)

Note 1 to entry: Maintenance can be necessary during the EXPECTED SERVICE LIFE.

[SOURCE: IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.28, modified – In the definition, 'ME EQUIPMENT and ME SYSTEM' have been replaced with 'MEDICAL DEVICE'.]

3.7
FORMATIVE EVALUATION
USER INTERFACE EVALUATION conducted with the intent to explore USER INTERFACE design strengths, weaknesses, and unanticipated USE ERRORS

Note 1 to entry: FORMATIVE EVALUATION is generally performed iteratively throughout the design and development PROCESS, but prior to SUMMATIVE EVALUATION, to guide USER INTERFACE design as necessary.

3.8
HAZARD-RELATED USE SCENARIO
USE SCENARIO that could lead to a HAZARDOUS SITUATION or HARM

Note 1 to entry: A HAZARD-RELATED USE SCENARIO can often be linked to a potential USE ERROR.

Note 2 to entry: A HAZARD-RELATED USE SCENARIO is not related to a failure of the MEDICAL DEVICE, unless the MEDICAL DEVICE failure was caused by a USE ERROR.

3.9
*** NORMAL USE**
operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those MEDICAL DEVICES provided without instructions for use

Note 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

Note 2 to entry: USE ERROR can occur in NORMAL USE.

Note 3 to entry: MEDICAL DEVICES that can be used safely without instructions for use are exempted from having instructions for use by some authorities with jurisdiction.

Note 4 to entry: Figure 1 shows the relationships of the types of use.

[SOURCE: IEC 60601-1:2005, 3.71, modified – Notes 2, 3 and 4 to entry have been added, and in the definition 'OPERATOR' has been replaced with 'USER' and the entire phrase after "instructions for use" has been added.]

3.10
*** PATIENT**
living being (person) undergoing a medical, surgical or dental PROCEDURE

Note 1 to entry: A PATIENT can be a USER.

[SOURCE: IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.76, modified – The phrase ‘or animal’ has been deleted from the definition and "USER" has been substituted for "operator" in the note to entry.]

3.11
*** PRIMARY OPERATING FUNCTION**
function that involves USER interaction that is related to the SAFETY of the MEDICAL DEVICE

Note 1 to entry: Often a PRIMARY OPERATING FUNCTION is interacted with by a series of TASKS that can be broken down into a series of USER interactions.

Note 2 to entry: The concept of SAFETY includes loss or degradation of performance resulting in an unacceptable RISK to the PATIENT, including USE ERROR that prevents the USER from effectively using the MEDICAL DEVICE to achieve its intended medical purpose. In IEC 60601-1, this is referred to as ‘essential performance’. .

3.12
RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of a MEDICAL DEVICE or combination of MEDICAL DEVICES

Note 1 to entry: The accountable entity can be, for example, a hospital, an individual clinician or a lay person. In home use applications, the PATIENT, USER and RESPONSIBLE ORGANIZATION can be one and the same person.

Note 2 to entry: Education and training are included in "use."

[SOURCE: IEC 60601-1:2005, 3.101, modified – The reference in the definition to ‘an ME EQUIPMENT or ME SYSTEM’ has been replaced with ‘a MEDICAL DEVICE OR COMBINATION OF MEDICAL DEVICES’ and 'operator' has been replaced by 'USER' in the note to entry.]

3.13
SUMMATIVE EVALUATION
USER INTERFACE EVALUATION conducted at the end of the USER INTERFACE development with the intent to obtain OBJECTIVE EVIDENCE that the USER INTERFACE can be used safely

Note 1 to entry: SUMMATIVE EVALUATION relates to validating the safe use of the USER INTERFACE.

3.14
TASK
one or more USER interactions with a MEDICAL DEVICE to achieve a desired result

Note 1 to entry: A TASK description should include the allocation of activities and operational steps between the USER and the MEDICAL DEVICE.

Note 2 to entry: TASKS should not be described solely in terms of the functions or features provided by the MEDICAL DEVICE.

3.15
UOUP
USER INTERFACE OF UNKNOWN PROVENANCE
USER INTERFACE or part of a USER INTERFACE of a MEDICAL DEVICE previously developed for which adequate RECORDS of the USABILITY ENGINEERING PROCESS of this standard are not available

Note 1 to entry: This note applies to the French version only.

3.16
*** USABILITY**
characteristic of the USER INTERFACE that facilitates use and thereby establishes EFFECTIVENESS, EFFICIENCY and USER satisfaction in the intended USE ENVIRONMENT

Note 1 to entry: All aspects of USABILITY, including EFFECTIVENESS, EFFICIENCY and USER satisfaction, can either increase or decrease SAFETY.

3.17
*** USABILITY ENGINEERING**
HUMAN FACTORS ENGINEERING
application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of MEDICAL DEVICES (including software), systems and TASKS to achieve adequate USABILITY

Note 1 to entry: Achieving adequate USABILITY can result in acceptable RISK related to use.

3.18
*** USABILITY ENGINEERING FILE**
set of RECORDS and other documents that are produced by the USABILITY ENGINEERING PROCESS

3.19
USABILITY TEST
method for exploring or evaluating a USER INTERFACE with intended USERS within a specified intended USE ENVIRONMENT

3.20
USE ENVIRONMENT
actual conditions and setting in which USERS interact with the MEDICAL DEVICE

Note 1 to entry: The conditions of use or attributes of the USE ENVIRONMENT can include hygienic requirements, frequency of use, location, lighting, noise, temperature, mobility, and degree of internationalization.

3.21
*** USE ERROR**
USER action or lack of USER action while using the MEDICAL DEVICE that leads to a different result than that intended by the MANUFACTURER or expected by the USER

Note 1 to entry: USE ERROR includes the inability of the USER to complete a TASK.

Note 2 to entry: USE ERRORS can result from a mismatch between the characteristics of the USER, USER INTERFACE, TASK, or USE ENVIRONMENT.

Note 3 to entry: USERS might be aware or unaware that a USE ERROR has occurred.

Note 4 to entry: An unexpected physiological response of the PATIENT is not by itself considered USE ERROR.

Note 5 to entry: A malfunction of a MEDICAL DEVICE that causes an unexpected result is not considered a USE ERROR.

Note 6 to entry: Figure 1 shows the relationships of the types of use.

3.22
*** USE SCENARIO**
specific sequence of TASKS performed by a specific USER in a specific USE ENVIRONMENT and any resulting response of the MEDICAL DEVICE

3.23
*** USE SPECIFICATION**
APPLICATION SPECIFICATION
summary of the important characteristics related to the context of use of the MEDICAL DEVICE

Note 1 to entry: The intended medical indication, PATIENT population, part of the body or type of tissue interacted with, USER PROFILE, USE ENVIRONMENT, and operating principle are typical elements of the USE SPECIFICATION.

Note 2 to entry: The summary of the MEDICAL DEVICE USE SPECIFICATION is referred to by some authorities having jurisdiction as the 'statement of intended use'.

Note 3 to entry: The USE SPECIFICATION is an input to determining the INTENDED USE of ISO 14971:2007.

3.24
*** USER**
person interacting with (i.e. operating or handling) the MEDICAL DEVICE

Note 1 to entry: There can be more than one USER of a MEDICAL DEVICE.

Note 2 to entry: Common USERS include clinicians, PATIENTS, cleaners, maintenance and service personnel.

3.25
USER GROUP
subset of intended USERS who are differentiated from other intended USERS by factors that are likely to influence USABILITY, such as age, culture, expertise or type of interaction with a MEDICAL DEVICE

3.26
*** USER INTERFACE**
means by which the USER and the MEDICAL DEVICE interact

Note 1 to entry: ACCOMPANYING DOCUMENTATION is considered part of the MEDICAL DEVICE AND ITS USER INTERFACE.

Note 2 to entry: USER INTERFACE includes all the elements of the MEDICAL DEVICE with which the USER interacts including the physical aspects of the MEDICAL DEVICE as well as visual, auditory, tactile displays and is not limited to a software interface.

Note 3 to entry: For the purposes of this standard, a system of MEDICAL DEVICES can be treated as a single USER INTERFACE.

3.27
USER INTERFACE EVALUATION
PROCESS by which the MANUFACTURER explores or assesses the USER interactions with the USER INTERFACE

Note 1 to entry: A USER INTERFACE EVALUATION may consist of one or more of the following techniques, amongst others, USABILITY TESTS, expert reviews, heuristic analyses, design audits or a cognitive walk through.

Note 2 to entry: USER INTERFACE EVALUATION is frequently performed iteratively throughout the design and development PROCESS (this is FORMATIVE EVALUATION).

Note 3 to entry: USER INTERFACE EVALUATION is a part of the activities involved in verifying and validating the overall MEDICAL DEVICE design (this is SUMMATIVE EVALUATION).

3.28
*** USER INTERFACE SPECIFICATION**
collection of specifications that comprehensively and prospectively describe the USER INTERFACE of a MEDICAL DEVICE

3.29
USER PROFILE
summary of the mental, physical and demographic traits of an intended USER GROUP, as well as any special characteristics, such as occupational skills, job requirements and working conditions, which can have a bearing on design decisions

4 Principles

4.1 General requirements

4.1.1 * USABILITY ENGINEERING PROCESS

The MANUFACTURER shall establish, document, implement and maintain a USABILITY ENGINEERING PROCESS, as defined in Clause 5, to provide SAFETY for the PATIENT, USER and others. The PROCESS shall address USER interactions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENTATION, including, but not limited to:

– * transport;
– * storage;
– installation;
– operation;
– maintenance and repair; and
– disposal.

USABILITY ENGINEERING activities for a MEDICAL DEVICE shall be planned, carried out, and documented by personnel competent on the basis of appropriate education, training, skills or experience.

Where a documented product realization PROCESS exists, such as that described in Clause 7 of ISO 13485:2003 [11], it shall incorporate the appropriate parts of or reference the USABILITY ENGINEERING PROCESS.

NOTE 1 Subclause 6.2 of ISO 13485:2003 contains additional information relating to personnel competence.

A depiction of the interrelationship between the RISK MANAGEMENT PROCESS of ISO 14971:2007 and the USABILITY ENGINEERING PROCESS described in this standard is shown in Figure A.4.

The activities described in Clause 5, as shown Figure A.4, are described in a logical order, but they may be carried out in a flexible order as appropriate.

Consider compliance with this subclause to exist when the requirements of this International Standard have been fulfilled.

4.1.2 * RISK CONTROL as it relates to USER INTERFACE design

To reduce use-related RISK, the MANUFACTURER shall use one or more of the following options, in the priority listed (as required by ISO 14971:2007, 6.2):

a) inherent SAFETY by design;
b) protective measures in the MEDICAL DEVICE itself or in the manufacturing PROCESS;
c) information for SAFETY.

NOTE Information for SAFETY can also be required by product standards and other sources.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

4.1.3 Information for SAFETY as it relates to USABILITY

When, in accordance with the priorities of 4.1.2, information for SAFETY is used as a RISK CONTROL measure, the MANUFACTURER shall subject this information to the USABILITY ENGINEERING PROCESS to determine that the information

– is perceivable by,
– is understandable to, and
– supports CORRECT USE of the MEDICAL DEVICE by

USERS of the intended USER PROFILES in the context of the intended USE ENVIRONMENT.

NOTE 1 The relationship between USER perception, cognition and action is shown in Figure A.1.

NOTE 2 Examples of information for SAFETY are found in IEC 62366-2.

Conscious disregard of such information for SAFETY by the USER is considered to be an intentional act or intentional omission of an act that is counter to or violates NORMAL USE and